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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,102	03/01/2002	Michael Flavin	01-128-A	4193

20306 7590 02/23/2005

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,102	FLAVIN ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 24, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Amendments of January 24, 2005 have been received and entered in full. Claims 1-20 are under examination. Claim 20 has been amended. The examiner incorrectly cited Amstrong as USPN 5,422,004 in the previous office action, the correct patent number is 5,874, 005. However the correct patent number was cited on form 892 enclosed with the previous action. Any rejections not repeated below have hereby been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amstrong (USPN 5,874,005 02/23/1999) in view of Agrafiotis et al. (USPN 5,684,711 11/04/1997).

Amstrong teaches to identify physical variables that affect chiral selectivity for the separation of racemic mixtures, one being stationary phases. He teaches to determine a range of values of the physical variables. He teaches a finite number of experimental tests. He teaches a plurality of stationary phases and a plurality of collection tubes. He teaches assigning the test stationary phase to a particular well, dispensing the racemic mixture solution into each of the stationary phases at a predetermined concentration, allowing the racemic mixture to pass through each stationary phase and collecting the solution in its corresponding tube. With regard to claim 5, he teaches determining an optimal racemic solution, having the highest selective adsorption, where the stationary phases are classified based on characteristics, and parameters for future experiments include stationary phases with the same

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characteristics as the stationary phase used for the optimal racemic solution (see whole document, specifically, examples 28 and 29, col. 29-32). With regard to claim 6, he teaches physical variables selected from the group of stationary phases, amount of stationary phase, racemic mixture solution concentration, and operating conditions (see tables 6-7). With regard to claims 7 and 18, he teaches physical variables as choice of solvents (see col. 14 lines 35-38). With regard to claim 8, he teaches physical variables as solvent percentages (see col. 14 lines 35-38). With regard to claim 9, he teaches determining enantiomeric excess (see table 9). With regard to claim 12, he teaches washing the stationary phase and re-using the phase for the next experiment (see col. 7 line 56). With regard to claim 13, he teaches assigning a stationary phase based on the parameters to a particular well, packing the test phase into the well, dispensing the racemic mixture into the different stationary phases, collecting the solution after it passes over the stationary phase and analyzing the solutions collected (see col. 16 table 9). With regard to claim 15, he further teaches analyzing to determine the magnitude of chiral resolution by determining optical rotation of the collected solution (see col. 21 lines 65-67, col. 22 lines 20-48). With regard to claim 16, he teaches a polarimeter as an analyzer (see col. 21 lines 65-67, col. 22 lines 20-48). With regard to claim 17, he teaches a chiral HPLC as an analyzer (see col. 23 line 6). With regard to claim 19, he teaches a choice of stationary phases (see col. 30 lines 52-64). With regard to claim 20 he teaches choosing a test stationary phase from a library of potential stationary phases, a finite number of experimental tests, which have the test stationary phases chosen. He teaches providing a plurality of stationary phases and a plurality of collection plates, passing the racemic solution through the stationary phases, collecting the solutions and analyzing the contents to determine the magnitude of the chiral resolution for the solution (see examples 28 and 29, col. 29-32).

With regard to claims 1, 14, 20, Armstrong does not teach automatically generating suggested parameters for future experiments using a computer, wherein the parameters are chosen from a new range of values based on the analysis of the plurality of racemic solutions collected. With regard to claim 2, he

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does not teach generating a statistical analysis based on the analysis of the plurality of racemic solutions collected, wherein generating suggested parameters for future experiments is based on the statistical analysis. With regard to claim 3, he does not teach generating the statistical analysis using the computer. With regard to claim 4, he does not teach generating statistical analysis includes determining an optimal racemic solution having the highest selective adsorption. With regard to claim 10, he does not teach washing the stationary phase is automated.

Agrafiotis et al. do teach automatically generating suggested parameters for future experiments using a computer, wherein the parameters are chosen from a new range of values based on the analysis of the plurality of solutions collected (see whole document, specifically Figs. 2-3). With regard to claim 2, they teach generating a statistical analysis based on the analysis of the plurality of solutions collected, wherein generating suggested parameters for future experiments is based on the statistical analysis (see Figs. 2-3). With regard to claim 3, they teach generating the statistical analysis using the computer (see Figs. 2-3). With regard to claim 4, they teach generating statistical analysis includes determining an optimal solution having the highest selective adsorption (see Figs. 2-3). With regard to claim 10, they teach automating experimental steps (see Figs. 2-3).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Agrafiotis's method of automation with Armstrong's method for comparing chiral stationary phases in order to evaluate a greater number of stationary phases more efficiently. Agrafiotis et al. state that an automated system provides more efficient evaluation of a plurality of structure-activity models in parallel. (col. 4 lines 11-13). It would have been prima facie obvious to apply Agrafiotis's automation to Armstrong's method for evaluating chiral stationary phases to achieve the expected advantage of greater efficiency in evaluating large numbers of chiral stationary phases in parallel.

Response to Arguments

4. Applicants' arguments filed January 24, 2005, have been fully considered but they are not persuasive.

With respect to the assertion by applicants' attorney that the office action is not sufficient, Applicants' attorney cites 35 CFR 1.104 (c)(2), the examiner assumes applicants' attorney means 37 CFR 1.104 (c)(2), for support that the examiner has not met the burden to specifically point out the particular part of a reference that is relied on. Applicants' attorney appears to argue the office action has failed to explain the pertinence of, for example, Example 31 to any independent claim. Applicants' attention is directed to the office action of record, a careful reading of which will show that Example 31 was not cited nor relied on to teach the invention. Further, the degree of complexity found in the art cited does not exceed that of an ordinary practitioner.

With respect to the 103 (a) rejections of claims 1-20, applicants' argue neither Amstrong nor Agrafiotis teach a plurality of wells in a sample plate a collection plate. Applicants' further argue failure to provide an objective reason to combine as well as hindsight language. Finally applicants' assert the references do expressly or impliedly suggest applicants' claimed invention. Agrafiotis et al., however, teach a plurality of wells in a sample and a collection plate, where the stationary phase is a support resin containing a library or plurality of chemicals and distributes the compounds into a 96 well plate or collection plate (see particularly, col. 8 line 40). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Agrafiotis provide clear motivation to automate with the statement "Under the system of the present

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invention, a plurality of structure-activity models may be tested and evaluated in parallel (see col. 4 lines 11-13). Further MPEP states,

Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See *Dann v. Johnston*, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976); *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

In response to applicants' argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Finally with respect to applicants' argument the references do not expressly or impliedly suggest the claimed invention, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The combination of *Amstrong* and *Agrafiotis* do teach the instant invention for the all of the reasons outlined above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing

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date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

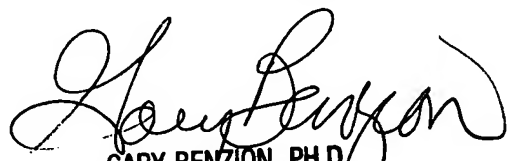
Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600